Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Blanche Manning	Sitting Judge if Other than Assigned Judge	Nan R. Nolan
CASE NUMBER	00 C 2855	DATE	2/16/2001
CASE TITLE	SmithKline Beecham Corporation, et al. vs. Pentech Pharmaceuticals, Inc.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] Enter Memorandum Opinion and Order: SmithKline's Motion for Leave to Amend Their Complaint to Add Asahi Glass as a Defendant [48-1] is granted. The Court grants SmithKline leave to file a Second Amended Complaint consistent with this opinion on or before February 23, 2001.

(11) ■ [For further detail see order attached to the original minute order.]

Judge E Manning

	No notices required, advised in open court.		number of notices
	No notices required.		
✓	Notices mailed by judge's staff.		FEB 20 2001 date docketed
	Notified counsel by telephone.		
	Docketing to mail notices.		docketing deputy initials
	Mail AO 450 form.		
✓	Copy to judge/magistrate judge.		date mailed notice
KMc	courtroom deputy's initials	01 FEB 16 PM 2:38 Date/time received in central Clerk's Office	mailing deputy initials

Document Number

68

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SMITHKLINE BEECHAM CORPORATION	)	
	)	
and	)	
	)	
BEECHAM GROUP, p.l.c.,	)	
	)	
Plaintiffs	)	**Case No. 00 C 2855**
	)	
v.	)	**Judge Blanche M. Manning**
	)	
PENTECH PHARMACEUTICALS, INC.	)	**Magistrate Judge Nan R. Nolan**
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Smithkline Beecham Corporation and Beecham Group, p.l.c. (collectively "Smithkline") have sued Defendant Pentech Pharmaceuticals, Inc. ("Pentech") for patent infringement. Smithkline's patents cover certain crystalline forms of paroxetine hydrochloride, the active ingredient in Smithkline's anti-depressant drug Paxil®. Smithkline moves for leave to amend the complaint to add Asahi Glass ("Asahi"), a Japanese company, as a defendant. For the reasons explained below, Smithkline's motion is GRANTED.

I. FACTS

The following facts are taken from Smithkline's proposed Second Amended Complaint. Smithkline is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world. Second Am. Cmplt. ¶ 4. Smithkline manufactures crystalline paroxetine hydrochloride hemihydrate in bulk form in the United Kingdom, and then tablets and sells the product in the United States under the trademark PAXIL®. Id. PAXIL® is

used to treat depression, panic disorder, and obsessive compulsive disorder. Id. According to Smithkline, PAXIL® is one of the most widely prescribed prescription drugs in the United States. Id. Beecham Group, p.l.c. owns U.S. Patent No. 4,721,723 ("the '723 patent") for an invention entitled "Anti-Depressant Crystalline Paroxetine." Id. ¶¶ 6, 7. Smithkline Beecham Corporation owns U.S. Patent Nos. 5,872,132 ("the '132 patent") and 5,900,423 ("the '423 patent") for inventions entitled "Form of Paroxetine Hydrochloride Anhydrate." Id. ¶¶ 8, 9.

Pentech is a corporation organized under the laws of the State of Illinois and maintains an office in Buffalo Grove, Illinois. Id. ¶ 10. Pentech is engaged in the business of developing generic pharmaceutical compounds. Id. Asahi Glass is a corporation organized under the laws of Japan and maintains an office at 2-1-2 Marunouchi, Chiyoda-ku, Toyko 100-8305, Japan. Id ¶ 11. Asahi is engaged in the business of manufacturing and marketing pharmaceutical compounds in the United States. Id.

The first three counts of Smithkline's proposed Second Amended Complaint allege that under 35 U.S.C. § 271(e)(2)(A), Pentech infringed the '723, '132, and '423 patents by submitting to the U.S. Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") seeking approval for the commercial marketing of its paroxetine hydrochloride drug product before the expiration date of Smithkline's patents, a product the manufacture, use, import, offer for sale, or sale of which will infringe the claims of the patents. Id. ¶¶ 12-21.

Smithkline's proposed amendment is to bring a fourth count of patent infringement against Asahi. Id. ¶¶ 22-24. Smithkline alleges that Asahi collaborated with Pentech in the research and development of Pentech's generic version of Paxil®, provided Pentech with paroxetine hydrochloride for use in clinical studies in support of Pentech's ANDA, and directed and encouraged

Pentech and the FDA to rely on information that Asahi submitted to the FDA in support of Pentech's ANDA, specifically, Asahi's Drug Master File ("DMF") No. 14432 for paroxetine hydrochloride.[1] Id. ¶ 23. Smithkline further alleges that Pentech relied before the FDA upon Asahi's DMF for a complete description of the paroxetine hydrochloride, including the manufacturing facilities and process, physical and chemical characteristics, and stability of the paroxetine hydrochloride made for Pentech. Id. Smithkline believes that the Asahi DMF describes the production of crystalline paroxetine hydrochloride which infringes Smithkline's '723, '132, and/or '423 patents. Id. If the FDA approves Pentech's ANDA, Asahi will be Pentech's solely approved manufacturer of the paroxetine hydrochloride to be used as the active ingredient in Pentech's generic drug product. Id.

Smithkline alleges that under 35 U.S.C. §§ 271(b) and (e)(2), Asahi infringed and actively, knowingly, and intentionally induced the infringement of Smithkline's '723, '132, and '423 patents by submitting, causing to be submitted, assisting with, participating in, contributing to, and/or supporting the submission of an ANDA to the FDA seeking approval for the commercial marketing of paroxetine hydrochloride tablets before the expiration of Smithkline's patents, a product the manufacture, use, import, offer for sale, or sale of which will infringe the claims of Smithkline's '723, '132, and '423 patents.

[1] "A drug master file is a submission of information to the [FDA] by a person (the drug master file holder) who intends it to be used for one of the following purposes: To permit the holder to incorporate the information by reference when the holder submits an investigational new drug application under Part 312 or submits an application or an abbreviated application or an amendment or supplement to them under this part, or to permit the holder to authorize other persons to rely on the information to support a submission to FDA without the holder having to disclose the information to the person." 21 C.F.R. § 314.420.

II. DISCUSSION

Leave to amend a complaint should be freely given "when justice requires." Fed. R. Civ. P. 15(a). However, leave to amend is "inappropriate where there is undue delay, bad faith, dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, or futility of the amendment." Perrian v. O'Grady, 958 F.2d 192, 194 (7th Cir. 1992).[2] "The opportunity to amend a complaint is futile if 'the complaint, as amended, would fail to state a claim upon which relief could be granted.'" General Elec. Capital Corp. v. Lease Resolution Corp., 128 F.3d 1074, 1985 (7th Cir. 1997) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997)).

A. Direct Infringement

Pentech first argues that it would be futile to allow Smithkline to add a claim against Asahi pursuant to 35 U.S.C. § 271(e)(2)(A) because no valid claim exists for alleging direct infringement by Asahi. Section 271(e)(2)(A) provides that "it shall be an act of infringement to submit" an ANDA if the purpose of such submission is to obtain FDA approval to commercially make, use, or sell a patented product or a product the use of which is patented before the patent expires. Pentech maintains that as a matter of law, a person other than the ANDA filer can not be held liable for direct

[2] Generally, when analyzing whether leave to amend should be granted in a patent infringement case, regional circuit law, rather than Federal Circuit law, applies. Cultor Corp. v. A.E. Stanley Manufacturing Company, 224 F.3d 1328, 1332 (Fed. Cir. 2000); Filmetec Corp. v. Hydranautics, 67 F.3d 931, 935 (Fed. Cir. 1995). However, Federal Circuit law is controlling as to issues that are unique to patent law. "[A] procedural issue that is not itself a substantive patent law issue is ... governed by Federal Circuit law if the issue pertains to patent law, if it bears an essential relationship to matters committed to [the Federal Circuit's] exclusive jurisdiction by statute, or if it clearly implicates the jurisprudential responsibilities of [the Federal Circuit] in a field within its exclusive jurisdiction." In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 803 (Fed. Cir. 2000).

infringement under section 271(e)(2)(A).

Asahi cannot be held liable as a direct infringer under section 271(e)(2)(a) because Asahi did not submit the ANDA at issue. Rather, Asahi is the bulk manufacturer of the paroxetine hydrochloride active ingredient in Pentech's drug product and submitted a DMF to the FDA describing the manufacture of paroxetine hydrochloride used in Pentech's generic version of Paxil®. Smithkline's interpretation of section 271(e)(2)(a) as allowing a person other than the ANDA filer to be held liable for direct infringement under that section is not supported by the plain language of the statute. The plain language of the statute controls. VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574, 1579 (Fed. Cir. 1990).[3] There is no reference in section 271(e)(2)(A) to suppliers of ingredients of generic drug products or preparers of DMFs relied on by ANDA filers. Section 271(e)(2)(A) unambiguously refers only to persons who submit ANDAs.

Smithkline has not presented, and the Court has been unable to locate, any authority supporting the proposition that a person other than an ANDA filer can be held liable for direct infringement under section 271(e)(2)(A). None of the cases cited by Smithkline involve the precise issue raised here. The two cases cited by Smithkline--Smithkline Beecham Corp., v. Apotex Corp., 2000 WL 983937 (N.D. Ill. July 17, 2000) and Eli Lilly and Co. v. Zenith Goldline Pharmaceuticals, Inc., 101 F.Supp.2d 1139, 1141 n.2 (S.D. Ind. 2000)--do not address the question of whether a non-ANDA filer can be held liable as a direct infringer under section 271(e)(2)(A) but rather merely mention that the plaintiffs in those actions alleged that non-filers were directly liable under section

[3] Whether Smithkline can state a claim for direct infringement against a person other than an ANDA filer under section 271(e)(2)(A) "clearly implicates substantive patent law," and Federal Circuit law controls.

271(e)(2)(A). Given the clear language of section 271(e)(2)(A), Smithkline has not provided any legitimate reason for inferring that third parties who did not file an ANDA can be directly liable under that section.

B. Inducement of Infringement

Pentech next argues that Smithkline fails to allege any facts to support an allegation of active inducement. Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Whether Smithkline's proposed complaint states a claim for inducement of infringement is determined by the law of the regional circuit, the Seventh Circuit. C&F Packing Co., Inc. v IBP, Inc., 224 F.3d 1296, 1306 (Fed. Cir. 2000); Phonometrics, Inc. v. Hospitality Franchise Systems, Inc., 203 F.3d 790, 793 (Fed. Cir. 2000).

Pentech maintains that Smithkline impermissibly pleads only the bare legal conclusion that Asahi "induced the infringement of" Smithkline's patents. Pentech complains that Smithkline alleges no facts to support this legal conclusion. Pentech misconstrues the requirements of notice pleading. Facts need not be pled with specificity under notice pleading. Federal Rule of Civil Procedure 8(a) requires only an identification of the basis of jurisdiction and a "short and plain statement of the claim showing that the pleader is entitled to relief." "A plaintiff in a suit in federal court need not plead facts; he can plead conclusions." Jackson v. Marion County, 66 F.3d 151, 153 (7th Cir. 1995). The conclusions need only provide the defendant with "at least minimal notice of the claim." Id. at 154.

Smithkline's allegations satisfy the liberal federal pleading standards. Smithkline alleges that Asahi intentionally induced the infringement of Smithkline's '723, '132, and '423 patents by causing to be submitted, assisting with, participating in, contributing to, and/or supporting the submission

of an ANDA to the FDA seeking approval for the commercial manufacture of paroxetine hydrochoride tablets before the expiration of Smithkline's patents, a product the manufacture, use, import, offer for sale, or sale of which will infringe the claims of Smithkline's patents. Second Am. Cmplt. ¶ 24. Smithkline further alleges that Asahi collaborated with Pentech in the research and development of Pentech's generic version of Paxil®, provided Pentech with paroxetine hydrochloride for use in clinical studies in support of Pentech's ANDA, and directed and encouraged Pentech and the FDA to rely on Asahi's Drug Master File in support of Pentech's ANDA. Id. ¶ 23. Because Pentech has the requisite minimal notice of Smithkline's inducement of infringement claim, it would not be futile to allow Smithkline to amend the complaint.[4]

C. **Permissive Joinder**

Smithkline's claim against Asahi also satisfies the requirements of permissive joinder. Federal Rule of Civil Procedure 20(a) provides that all persons may be joined in one action as defendants "if there is asserted against them jointly, severally, or in the alternative, any right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of law or fact common to all defendants will arise in the action."

[4] In Torpharm v. Novopharm, 181 F.R.D. 308 (E.D. N.C. 1998), cited by Pentech, Torpharm sought leave to file an amended complaint adding Genpharm as a defendant. Torpharm's proposed amendment asserted a claim for inducement of infringement against Genpharm pursuant to section 271(b). Genpharm had no involvement with the filing of the alleged direct infringer's ANDA and merely waived its exclusivity period for the direct infringer. The district court denied Torpharm's motion to amend as futile because Torpharm failed to allege any facts which showed intent to induce infringement. Torpharm is distinguishable from this case because Smithkline alleges that Asahi was involved in the filing of Smithlkine's ANDA by collaborating with Pentech in the research and development of Pentech's generic drug product, providing Pentech with the bulk active ingredient for use in clinical studies, and by directing Pentech and the FDA to rely on Asahi's DMF in support of Pentech's ANDA. Smithkline expressly alleges that by these actions Asahi participated in the submission of Pentech's ANDA and intentionally induced the infringement of Smithkline's patents.

The claims against Pentech and Asahi arise out of the same transaction or occurrence. Specifically, the claims relate to the submission of Pentech's ANDA to the FDA supported in part by Asahi's DMF and clinical studies using Asahi's bulk paroxetine hydrochloride. The question of law common to both defendants is whether the manufacture, use, or sale of the generic drug product that Pentech is likely to sell will infringe Smithkline's patents. The resolution of that issue depends in part on whether the paroxetine hydrochloride that Asahi makes and supplies to Pentech will infringe one or more of Smithkline's patents.

Pentech relies on Smith v. City of Chicago Police Dept., 1989 WL 55045 (N.D. Ill. May 12, 1989), for the proposition that joinder should be denied because joinder would afford Smithkline no "additional basis for relief." Smith is easily distinguishable and provides no valid ground for denying joinder here. Smith alleged that his arrest in October 1978 violated his constitutional rights. The district court held that res judicata and collateral estoppel prevented Smith from raising claims regarding his arrest against defendants. The court then denied Smith leave to join additional defendants because Smith was "absolutely foreclosed from relitigating any issues associated with his arrest, whether it be against the same parties (and their privies) or any new parties." Id. at *7. In contrast to Smith, res judicata and collateral estoppel have no application here. Smithkline is not foreclosed from litigating any issues related to Pentech's ANDA seeking FDA approval to market capsules containing a form of paroxetine hydrochloride as the active ingredient.

III. CONCLUSION

For the reasons set forth above, Smithkline's Motion for Leave to Amend Their Complaint to Add Asahi Glass as a Defendant is GRANTED. The Court grants Smithkline leave to file a Second Amended Complaint consistent with this opinion on or before February 23, 2001.

ENTER:

Nan R. Nolan

Nan R. Nolan
United States Magistrate Judge

Dated: Feb. 16, 2001